UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

ARTEMUS BANKS, Plaintiff, v. BAXTER INTERNATIONAL, INC., a corporation; BAXTER HEALTHCARE CORPORATION, a corporation, and SCIENTIFIC PROTEIN LABORATORIES, LLC, a limited liability company, ROBERT L. PARKINSON, JR., JAMES M. GATLING, and DAVID ROHRBACH, Defendants.	)	Case No. 08-cv-02324 Hon. Judge Robert W. Gettleman Magistrate Judge Mason

MOTION FOR ORDER TO PRESERVE EVIDENCE

NOW COMES Plaintiff, Artemus Banks, by and through his attorneys, Nolan Law Group, and moves this Honorable Court for the entry of an Order preserving and protecting evidence relevant to his cause of action, namely those Heparin products returned to them or otherwise in their possession and in support hereof states as follows:

1. Plaintiff filed a complaint alleging injuries sustained as the result of a defective Heparin drug product manufactured by Defendants. (See Exhibit A) Specifically, plaintiff used Heparin during his home dialysis which came from Lot Number 027020 and bearing corresponding National Drug Code ("NDC") 0641-2450-41. (Exhibit A at ¶31)

2. Defendants, Baxter International, Inc., and Baxter Healthcare Corporation (collectively "Baxter") issued a first Urgent Product Recall letter on January 17, 2008 relating to nine lots of the Heparin product with certain NDC identifications corresponding thereto. (See Exhibit B).

3. On January 24, 2008, Baxter issued an "Additional Information" letter clarified the prior Urgent Recall Letter to include the NDC on the actual vials subject to the recall which included NDC 0641-2450-41. (See Exhibit C).

4. On February 29, 2008, Baxter issued a second Urgent Product Recall letter to include additional Heparin Products including those in Lot Number 027020. (See Exhibit D).

5. Plaintiff first became aware of the Baxter recall in a letter from his Heparin distributor, Fresenius Medical Care dated March 12, 2008. (See Exhibit E).

6. In accordance with the Fresenius letter he received, plaintiff called to arrange return of his Heparin vials.

7. The Heparin products returned to defendants Baxter or otherwise in their possession ought to be preserved and protected by Order of this Court. A party has a duty to preserve evidence over which it has or had control and "reasonably knew or could reasonably foresee was material to a potential legal action." Wiginton v. Ellis, 2003 WL 22439865, *4 (Oct. 27, 2003) *citing* China Ocean Shipping (Group) Co., v. Simone Metals Inc., 1999 WL 966443 *3 (N.D.Ill. Sept. 30, 1999) (collecting cases)

8. Under Rule 26, "a party must preserve that evidence that is properly discoverable." Wiginton, supra. As this Court is well aware, preservation is interpreted broadly to accomplish the goal of maintaining the integrity of all documents, data and tangible things reasonably anticipated to be the subject of discovery under Fed. R.Civ. P. 26, 45 and 56(e).

9. Moreover, "[r]elevant information need not be admissible at the trial if the discovery appears reasonably calculated to lead to the discovery of admissible evidence."

Fed.R.Civ.P. 26(b)(1). The actual product subject to plaintiff's product liability action is highly relevant to plaintiff's claims and an entry of an order preserving and protecting the Heparin from alteration destruction and/or modification remains appropriate. Here, the Heparin originating from Lot Number 027020 and bearing corresponding National Drug Code ("NDC") 0641-2450-41 was ingested by plaintiff and subject to the recall orchestrated by defendants. Such highly relevant physical evidence is in the possession and/or control of defendants and is ultimately discoverable.

10. Accordingly, defendants will not need to undertake "extraordinary measures" to preserve all potential evidence. China Ocean Shipping (Group) Co, 1999 WL 966443 at *3; Danis v. USN Communications, Inc., 2000 WL 1694325 *32 (N.D.Ill. Oct. 20, 2000). On the other hand, plaintiff will be irretrievably prejudiced upon the destruction, modification, alternation of the subject Heparin. An order protecting and preserving this evidence ought to issue.

11. Indeed, the Illinois Supreme Court has gone so as far as declaring even the *potential* litigant owes a duty to preserve evidence. Shimanovsky v. General Motors Corp., 181 Ill.2d 112, 692 N.E.2d 286 (1998) (Potential litigant required to take reasonable measures to preserve the integrity of relevant material evidence for purposes of pretrial discovery); Farley Metals v. Barber Coleman Co., 269 Ill.App.3d 104, 645 N.E.3d 964 (1st Dist. 1994) (Rejecting argument that litigant did not intentionally destroy evidence, dismissal order was affirmed finding that the loss of evidence greatly prejudiced party forced to prepare its case with secondary evidence) This duty is founded upon the Illinois Supreme Court's concern that "were it unable to sanction a party for the *pre-suit* destruction of evidence, a potential litigant could circumvent discovery rules or

escape liability simply by destroying the proof prior to the filing of a complaint." Shimanovsky, 181 Ill.2d at 121 (Emphasis added)

12. As applied to the case at bar, these defendants have long been on notice that the Heparin returned by the plaintiff in response to defendants recall could potentially be the subject of litigation. Wiginton, 2003 WL 22439865 at *4 citing Cohn v. Taco Bell Corp., 1995 WL 519968 at *5 (N.D.Ill. Aug. 30, 1995); Wm.T. Thompson Co., v. Gen. Nutrition Corp., 593 F.Supp. 1443, 1455 (D.C. Cal. 1984). It is well established that a party may be alerted that certain information is likely to be sought in discovery before or upon the filing of a complaint. Id. citing Cohn, 1995 WL 519968 at *5.

13. Provided the minimal burden to defendants and the irretrievable prejudice resulting to plaintiff from the potential destruction of evidence, an order ought to issue preventing the destruction, modification and alteration of the Heparin products returned to defendants Baxter or otherwise in their possession for a period during the subject litigation and for a reasonable period thereafter.

14. Consistent with Local Rule 37.2, plaintiff's counsel took reasonable measures to resolve this matter by consultation with defendants' attorneys before seeking intervention from this Court. In a good faith attempt to resolve this matter, on May 5, 2008 and on May 6, 2008, Mollie E. O'Brien, one of the attorneys for plaintiff called Leslie Smith, one of the attorneys for Defendants Baxter. On May 7, 2008 plaintiff's counsel spoke over the telephone with defendants in an attempt to resolve this matter but were unable to reach an accord. A letter dated May 8, 2008 memorializes the substance of these discussions. (See Exhibit F)

WHEREFORE, Plaintiff, Artemus Banks, prays that this Court enter an order requiring Defendants, Baxter International, Inc. and Baxter Healthcare Corporation to preserve and protect all Heparin products returned to them or otherwise in their possession including that from Lot Number 027020 and those bearing NDC 0641-2450-41 until further order of Court.

Dated: May 9, 2008

Respectfully Submitted,

/s/ Donald J. Nolan, Esq.
Donald J. Nolan
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Attorneys for Plaintiff

CERTIFICATE OF SERVICE

I, Paul R. Borth, do hereby certify that on May 9, 2008, I caused a copy of the forgoing Motion for Order to Preserve Evidence to be served on Defendants' counsel by overnight delivery and electronically filed the foregoing document with the Clerk of Court using the CM/ECF system which will send notification of such filing to:

Leslie M. Smith, P.C.
Kirkland & Ellis, LLP
200 East Randolph Drive
Chicago, IL 60601
Tel: (312)861.2141

Attorneys for Baxter Healthcare Corp., Baxter International, Inc., Robert L. Parkinson & James M. Gatling, Defendants

EXHIBIT "A"

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

ARTEMUS BANKS, Plaintiff, vs. BAXTER INTERNATIONAL, INC., a corporation; BAXTER HEALTHCARE CORPORATION, a corporation, and SCIENTIFIC PROTEIN LABORATORIES, LLC, a limited liability company, ROBERT L. PARKINSON, JR., JAMES M. GATLING, and DAVID ROHRBACH, Defendants.	)	Case No. **FILED: APRIL 23, 2008** **08CV2324 AEE** **JUDGE GETTLEMAN** **MAGISTRATE JUDGE MASON** **PLAINTIFF DEMANDS TRIAL BY JURY**

COMPLAINT

Now comes the Plaintiff, ARTEMUS BANKS, by and through his attorneys, NOLAN LAW GROUP, and for his Complaint states as follows:

PARTIES

1. Plaintiff, ARTEMUS BANKS, is a resident of the State of Kentucky.

2. Defendant, BAXTER INTERNATIONAL, INC. is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business located within the State of Illinois and this District.

3. Defendant, BAXTER HEALTHCARE CORPORATION is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business located within the State of Illinois and this District, and is a wholly-owned subsidiary of Defendant, BAXTER INTERNATIONAL, INC.

4. Defendants, BAXTER INTERNATIONAL, INC. and BAXTER HEALTHCARE CORPORATION developed, formulated, manufactured, marketed, distributed, and sold the pharmaceutical Heparin.

5. Defendant, SCIENTIFIC PROTEIN LABORATORIES, L.L.C., is a limited liability company organized and existing under the laws of the State of Delaware with its principal place of business in the State of Wisconsin, and controls 55% of the interest in a joint venture known as Changzhou SPL Co. Ltd.

6. Defendant, SCIENTIFIC PROTEIN LABORATORIES, L.L.C. manufactures the active pharmaceutical ingredient ("API") for the Heparin, at its facility in Waunakee, Wisconsin and at its Changzhou SPL facility in China. Defendant, SPL, sells that API for inclusion in Heparin finished at the facilities of Defendants, BAXTER INTERNATIONAL, INC. and BAXTER HEALTHCARE CORPORATION.

7. Defendant, ROBERT L. PARKINSON is a resident of the State of Illinois and is and at all times relevant herein was the Chairman of the Board and Chief Executive Officer of Defendant, BAXTER INTERNATIONAL, INC.

8. Defendant, JAMES M. GATLING is a resident of the State of Illinois and is and at all times relevant herein was Corporate Vice President, Global Manufacturing Operations and Supply Chain Operations of Defendant, BAXTER INTERNATIONAL, INC.

9. Defendant, DAVID ROHRBACH is a resident of the State of Illinois and is and at all times relevant herein was Vice President, Quality of the Baxter Pharmaceuticals and Technologies Division of Defendant, BAXTER HEALTHCARE CORPORATION.

JURISDICTION AND VENUE

10. Plaintiff alleges an amount in controversy in excess of $75,000.00 exclusive of interest and costs. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332, because there is complete diversity of citizenship between Plaintiff and Defendants.

11. Venue is proper in the Northern District of Illinois pursuant to 28 U.S.C. § 1391. All Defendants reside in this District and/or are subject to personal jurisdiction within this District, and a substantial part of the events or omissions giving rise to this claim occurred in this District.

BACKGROUND FACTS

12. Plaintiff, ARTEMUS BANKS, seeks judgment against all defendants for compensatory and punitive damages arising from personal injuries he suffered from the use of a pharmaceutical drug commonly known as Heparin manufactured and distributed by Defendants BAXTER INTERNATIONAL, INC., BAXTER HEALTHCARE CORPORATION and SCIENTIFIC PROTEIN LABORATORIES, L.L.C.

13. The active pharmaceutical ingredient (API) in Heparin is sourced from pig intestines and then goes through multiple purification steps to inactivate proteins and viruses and to extract out contaminants before it reaches its final dosage form.

14. On March 19, 2008, Dr. Janet Woodcock, Director of the Center for Drug Evaluation and research for the United States Food and Drug Administration (FDA) announced at a press conference that testing had revealed a contaminant in certain Heparin API known as an over-sulfated chondroitin sulfate.

15. Chondroitin sulfate and heparin are each variably sulfated glycosaminoglycans ("GAGs") belonging to a group of chemicals known as complex polysaccharides. Chondroitin

sulfate is ordinarily purified from animal cartilage and is used in the United States as a dietary supplement to treat arthritis.

16. Over-sulfated chondroitin sulfate is not ordinarily found in nature. Most probably, ordinary chondroitin sulfate was chemically modified to introduce the additional sulfate groups found in the Heparin API during the course of the FDA supervised testing of the contaminated Heparin.

17. Over-sulfated chondroitin sulfate is not a drug approved by the FDA for use in the United States nor should it be present in heparin. Unlike conventional chondroitin sulfate, over-sulfated chondroitin sulfate mimics Heparin's activities in certain tests, including certain potency assays.

18. On November 19, 2007, doctors at St. Louis Children's Hospital treated a child who suffered allergic reactions from Heparin, including swollen lips and eyelids and a drop in blood pressure within minutes after dialysis.

19. Defendants, BAXTER INTERNATIONAL, INC. and BAXTER HEALTHCARE CORPORATION, through a spokeswoman has represented that the Defendants, BAXTER INTERNATIONAL, INC. and BAXTER HEALTHCARE CORPORATION, began an investigation when other physicians notified it of problems in late December, 2007.

20. The Centers for Disease Control and Prevention ("CDC") was first notified on January 7, 2008, by the Missouri Department of Health and Senior Services (MDHSS) of the allergic-type reactions among pediatric hemodialysis patients that began occurring November 19, 2007 at St. Louis Children's Hospital. The reactions had been reported to MDHSS by a health-care provider at the hospital. A total of eight episodes of acute allergic-type reactions were identified

as occurring among four patients at St. Louis Children's Hospital during the period of November 19, 2007 to January 15, 2008.

21. Government officials at the FDA stated that agency became aware of a potential problem with heparin product in early to mid January through reports it was receiving from Defendants, BAXTER INTERNATIONAL, INC. and BAXTER HEALTHCARE CORPORATION, and the CDC. Review of the FDA's Adverse Event Reporting system data revealed a spike in the number of reports coming into the FDA related to Heparin toward the end of December, 2007 and an escalation in January, 2008.

22. Defendants BAXTER INTERNATIONAL, INC. and BAXTER HEALTHCARE CORPORATION issued a first Urgent Product Recall letter on January 17, 2008 relating to certain Heparin products contained in Heparin Sodium Injection 1000 units/mL 10 mL vials bearing lot numbers 107054 and 117085 and Heparin Sodium Injection 1000 units/mL 30 mL vials bearing lot numbers 047056, 097081, 107024, 107064, 107066, 107074, and 107111.

23. On February 29, 2008, the Defendants, BAXTER INTERNATIONAL, INC. and BAXTER HEALTHCARE CORPORATION issued an additional Urgent Product Recall to include all lots of single and multi-dose vials of Heparin Sodium Injection product and another Urgent Product Recall to include recall of all lots of HEP-LOCK (Heparin Lock Flush Solution, USP) and HEP-LOCK U/P (Preservative-Free Heparin Lock Flush, USP) product.

24. The joint venture entity of the Defendant, SCIENTIFIC PROTEIN LABORATORIES, L.L.C., known as Changzhou SPL Co. Ltd. (and sometimes referred to as Changzhou Kaipu Biochemical Co. Ltd. or Changzhou Kaipu) submitted an application to the FDA for approval of the manufacturing of Heparin Sodium USP on May 10, 2002, which application was approved by the FDA in 2004.

25. Defendant, SCIENTIFIC PROTEIN LABORATORIES, L.L.C., manufactures finished Heparin API from raw materials procured in each North America and China. "Product 1060" identifies Heparin Sodium USP finished from Chinese raw materials at the Changzhou SPL facility, "Product 1035" identifies Heparin Sodium USP finished from Chinese raw materials at the SPL facility in Waunakee, Wisconsin, and "Product 1037" identifies Heparin Sodium USP finished from North American raw materials at the SPL facility in Waunakee, Wisconsin.

26. Since the date of approval by the FDA, Changzhou SPL Co., Ltd. has held and continues to hold FDA approval to manufacture Heparin Sodium USP in Jiangsu Province, China in accordance with the provisions of FDA Drug Master File Number 15973.

27. The Changzhou SPL facility was not inspected by the FDA prior to providing its manufacturing approval or at any other time prior to February 20, 2008.

28. The FDA conducted an inspection of the Changzhou SPL plant in China during the period of February 20-26, 2008. The FDA cited Changzhou SPL Company, Ltd. for a number of violations, including a) incomplete manufacturing instructions, b) lack of critical processing steps or annual test results, c) lack of an impurity profile for Heparin, d) incomplete manufacturing instructions for Heparin Sodium USP, e) investigations into failed lots were approved as complete, but no cause was listed, and f) inadequate control of material flow in the processing area.

29. A group of employees and agents of Defendants, BAXTER INTERNATIONAL, INC. and BAXTER HEALTHCARE CORPORATION inspected the Changzhou SPL facility in China in September 2007. At this point in time, if not sooner, Defendants BAXTER INTERNATIONAL, INC., BAXTER HEALTHCARE CORPORATION and SCIENTIFIC PROTEIN LABORATORIES, L.L.C., and each of them, knew of the unsafe and dangerous

conditions existing in the manufacturing process of Heparin API at the Changzhou SPL facility and the likelihood that harm to persons would result from these conditions.

FACTS APPLICABLE TO THE NAMED PLAINTIFF

30. At all times herein relevant, the Plaintiff, ARTEMUS BANKS, was receiving home dialysis as treatment for a medical condition and was prescribed Heparin for use during his home dialysis.

31. In or about January, 2008, Plaintiff, ARTEMUS BANKS, was delivered a box containing 25 vials of Baxter Heparin for use during his home dialysis known as Heparin Sodium Injection 1000 units/mL 30 mL bearing NDC 0641-2450-41 and Lot Number 027020 ("Subject Heparin Product") that was manufactured and distributed by Defendants, BAXTER INTERNATIONAL, INC. and/or BAXTER HEALTHCARE CORPORATION, and containing the Heparin API product ("Subject Heparin API") manufactured and distributed by the Defendant, SCIENTIFIC PROTEIN LABORATORIES, L.L.C.

32. Plaintiff, ARTEMUS BANKS, used the aforesaid Heparin product as prescribed and indicated, yet during the course of its use, Plaintiff ARTEMUS BANKS began experiencing numerous physical symptoms including suffered wheezing, shortness of breath, coughing, dizziness, increased perspiration and sudden weakness.

33. On or about March 12, 2008, Plaintiff, ARTEMUS BANKS, received a letter entitled "URGENT Baxter Heparin Recall" from Fresenius Medical Care instructing him to discontinue the use of the Heparin product and to make arrangements for return of the product with which he complied.

FIRST CAUSE OF ACTION
Products Liability v. Baxter and Baxter Healthcare

34. Plaintiff repeats and incorporates by reference paragraphs 1 through 33, inclusive, of this Complaint as fully set forth herein.

35. That at the time the Subject Heparin Product left the control of the defendants, BAXTER INTERNATIONAL, INC. and BAXTER HEALTHCARE CORPORATION, and each of them, it contained one or more conditions which rendered it defective and not reasonably safe when used in a reasonably foreseeable manner, including but not limited to the following:

(a) said Heparin product was manufactured, distributed and sold when it contained animal cartilage and/or other impurities that were injurious to the human body;

(b) said Heparin product was manufactured, distributed and sold without proper and adequate warnings and/or instructions to assist consumers and health care providers in identifying adverse reactions arising from the condition of the product; and/or

(c) said Heparin product was otherwise defective by way of its manufacture, distribution, sale, warnings and/or instructions in particulars to be determined through discovery in this action.

36. That as a direct and proximate result of one or more of the foregoing unreasonably dangerous conditions of the Subject Heparin Product, Plaintiff, ARTEMUS BANKS, suffered serious physical, mental and emotional injuries, some or all of which are permanent in nature.

37. That as a result of the aforesaid injuries, Plaintiff, ARTEMUS BANKS, was caused to and will in the future experience great pain and suffering, has suffered and will in the future suffer disability and disfigurement, has been caused to incur and will in the future incur expenses for necessary medical care, treatment and services, has suffered and will in the future suffer a loss of the value of his time, earnings, profits and salaries and has been and will be damaged in his earning capacity, and has otherwise been damaged in a personal and pecuniary nature.

WHEREFORE, Plaintiff, ARTEMUS BANKS, prays that judgment be entered in his favor and against the Defendants, BAXTER INTERNATIONAL, INC. and BAXTER HEALTHCARE CORPORATION, and each of them, in a sum in excess of seventy-five thousand dollars ($75,000), exclusive of interest and costs of this action.

SECOND CAUSE OF ACTION
Negligence – Baxter and Baxter Healthcare

38. Plaintiff repeats and incorporated by reference paragraphs 1 through 33 of this complaint as if fully set forth herein.

39. That it then and there became and was the duty of the Defendants, BAXTER INTERNATIONAL, INC. and BAXTER HEALTHCARE CORPORATION, and each of them, to exercise ordinary care in their conduct so as not to cause injury to the person of the Plaintiff, ARTEMUS BANKS.

40. Notwithstanding, the Defendants, BAXTER INTERNATIONAL, INC. and BAXTER HEALTHCARE CORPORATION, and each of them, breached their respective duty of care to the Plaintiff, ARTEMUS BANKS, through acts or omissions including but not limited to one or more of the following:

(a) negligently and carelessly procured bio-medical products from suppliers in China for use in pharmaceutical drugs in the United States, when the facilities and operations of those suppliers had never been properly or adequately inspected by or on behalf of Defendants, BAXTER INTERNATIONAL, INC. and/or BAXTER HEALTHCARE CORPORATION;

(b) negligently and carelessly failed to properly and adequately inspect and test the said Heparin product for unsafe and dangerous impurities contained therein;

(c) negligently and carelessly failed to employ proper and adequate quality control procedures to ensure that its Heparin product was safe and free from dangerous impurities;

(d) negligently and carelessly failed to properly supervise, monitor and/or oversee the acts and omissions of its Global Manufacturing Operations and Supply Chain Operations;

(e) negligently and carelessly failed to timely recall the said Heparin product or otherwise remedy the danger the product posed to consumers once the defendants, and each of them, became aware that a potential danger to consumers existed;

(f) negligently and carelessly manufactured, sold and distributed said Heparin product containing animal cartilage and/or other impurities that were injurious to the human body;

(g) negligently and carelessly manufactured, sold and distributed said product without proper and adequate warnings and/or instructions to assist consumers and health care providers in identifying adverse reactions arising from the condition of the product; and/or

(h) otherwise negligently and carelessly manufactured, sold and distributed said product when it was in an unsafe and dangerous condition by way of its manufacture, distribution, sale, warnings and/or instructions in particulars to be determined through discovery in this action.

41. That as a direct and proximate result of one or more of the beach of duty by the Defendants, BAXTER INTERNATIONAL, INC., and BAXTER HEALTHCARE CORPORATION, and each of them, Plaintiff, ARTEMUS BANKS, suffered serious physical, mental and emotional injuries, some or all of which are permanent in nature.

42. That as a result of the aforesaid injuries, Plaintiff, ARTEMUS BANKS, was caused to and will in the future experience great pain and suffering, has suffered and will in the future suffer disability and disfigurement, has been caused to incur and will in the future incur expenses for necessary medical care, treatment and services, has suffered and will in the future suffer a loss of the value of his time, earnings, profits and salaries and has been and will be damaged in his earning capacity, and has otherwise been damaged in a personal and pecuniary nature.

WHEREFORE, Plaintiff, ARTEMUS BANKS, prays that judgment be entered in his favor and against the Defendants, BAXTER INTERNATIONAL, INC. and BAXTER HEALTHCARE CORPORATION, and each of them, in a sum in excess of seventy-five thousand dollars ($75,000), exclusive of interest and costs of this action.

THIRD CAUSE OF ACTION
Breach of Warranties – Baxter and Baxter Healthcare

43. Plaintiff repeats and incorporates by reference paragraphs 1 through 33 of this Complaint as fully set forth herein.

44. Defendants, BAXTER INTERNATIONAL, INC. and BAXTER HEALTHCARE CORPORATION, and each of them, expressly and/or impliedly warranted and represented that the said Heparin product, including its instructions and warnings, conformed to manufacturing specifications, was proper and safe for the use for which it was manufactured and sold, and said defendants further warranted that the said Heparin product was free from defects.

45. Defendants, BAXTER INTERNATIONAL, INC. and BAXTER HEALTHCARE CORPORATION, and each of them, breached said warranties in that the said Heparin product did not conform to manufacturing specifications, was not proper and safe for the use for which it was manufactured and sold, and further was not free from defects.

46. Plaintiff, ARTEMUS BANKS, by way of his purchase and/or receipt of the said Heparin product, was a beneficiary of the warranties extended by Defendants, BAXTER INTERNATIONAL, INC. and BAXTER HEALTHCARE CORPORATION, and each of them.

47. As a direct and proximate result of the foregoing breach of warranties, by Defendants, BAXTER INTERNATIONAL, INC. and BAXTER HEALTHCARE CORPORATION, and

each of them, Plaintiff, ARTEMUS BANKS, suffered serious physical, mental and emotional injuries, some or all of which are permanent in nature.

48. That as a result of the aforesaid injuries, Plaintiff, ARTEMUS BANKS, was caused to and will in the future experience great pain and suffering, has suffered and will in the future suffer disability and disfigurement, has been caused to incur and will in the future incur expenses for necessary medical care, treatment and services, has suffered and will in the future suffer a loss of the value of his time, earnings, profits and salaries and has been and will be damaged in his earning capacity, and has otherwise been damaged in a personal and pecuniary nature.

WHEREFORE, Plaintiff, ARTEMUS BANKS, prays that judgment be entered in his favor and against the Defendants, BAXTER INTERNATIONAL, INC., and BAXTER HEALTHCARE CORPORATION, and each of them, in a sum in excess of seventy-five thousand dollars ($75,000), exclusive of interest and costs of this action.

FOURTH CAUSE OF ACTION
Willful & Wanton Misconduct – Baxter, Baxter Healthcare and Individual Defendants

49. Plaintiff repeats and incorporated by reference paragraphs 1 through 48 of this complaint as if fully set forth herein.

50. That the foregoing acts and omissions committed by the Defendants, BAXTER INTERNATIONAL, INC., and BAXTER HEALTHCARE CORPORATION, and each of them, were committed willfully and wantonly, were grossly negligent, and/or exhibited a conscious disregard for the safety and health of the general public, including the plaintiff.

51. That on numerous occasions prior to issuing the Urgent Product Recall letter on January 17, 2008, and in the period between January 17, 2008 and the issuing of the additional Urgent Product Recall letter on February 29, 2008, the Defendants, ROBERT L. PARKINSON, JR.,

JAMES M. GATLING, and DAVID ROHRBACH, and each of them had actual knowledge of the significant danger and risk of harm existing and its potential for injury, participated in meetings on behalf of Defendants, BAXTER INTERNATIONAL, INC., and BAXTER HEALTHCARE CORPORATION, in which the risks and dangers were discussed, and nevertheless made the conscious decision to not send an Urgent Product Recall letter prior to January 17, 2008, and withheld the additional Urgent Product Recall until February 29, 2008.

52. The foregoing acts and omissions of the Defendants, ROBERT L. PARKINSON, JR., JAMES M. GATLING, and DAVID ROHRBACH, and each of them, were committed willfully and wantonly, were grossly negligent, and/or exhibited a conscious disregard for the safety and health of the general public, including the plaintiff.

53. That as a result of the willful, wanton, and grossly negligent misconduct of the Defendants, BAXTER INTERNATIONAL, INC., BAXTER HEALTHCARE CORPORATION ROBERT L. PARKINSON, JR., JAMES M. GATLING, and DAVID ROHRBACH, and each of them, Plaintiff, ARTEMUS BANKS, suffered serious physical, mental and emotional injuries, some or all of which are permanent in nature.

54. That as a result of the aforesaid injuries, Plaintiff, ARTEMUS BANKS, was caused to and will in the future experience great pain and suffering, has suffered and will in the future suffer disability and disfigurement, has been caused to incur and will in the future incur expenses for necessary medical care, treatment and services, has suffered and will in the future suffer a loss of the value of his time, earnings, profits and salaries and has been and will be damaged in his earning capacity, and has otherwise been damaged in a personal and pecuniary nature.

WHEREFORE, Plaintiff, ARTEMUS BANKS, prays that judgment be entered in his favor and against the Defendants, BAXTER INTERNATIONAL, INC., BAXTER

HEALTHCARE CORPORATION, ROBERT L. PARKINSON, JR., JAMES M. GATLING, and DAVID ROHRBACH, and each of them, for compensatory damages in a sum in excess of seventy-five thousand dollars ($75,000), exclusive of interest and costs of this action, and for punitive damages in the amount of one hundred million dollars ($100,000,000.00).

FIFTH CAUSE OF ACTION
Product Liability – Scientific Protein Labs

55. Plaintiff repeats and incorporates by reference paragraphs 1 through 33, inclusive, of this Complaint as fully set forth herein.

56. That at the time the Subject Heparin API left the control of the Defendant, SCIENTIFIC PROTEIN LABORATORIES, L.L.C., it contained one or more conditions which rendered it defective and not reasonably safe when used in a reasonably foreseeable manner, including but not limited to the following:

(a) the Subject Heparin API was manufactured, distributed and sold when it contained animal cartilage and/or other impurities that were injurious to the human body;

(b) the Subject Heparin API was manufactured, distributed and sold without proper and adequate warnings and/or instructions to assist consumers and health care providers in identifying adverse reactions arising from the condition of the product; and/or

(c) the Subject Heparin API was otherwise defective by way of its manufacture, distribution, sale, warnings and/or instructions in particulars to be determined through discovery in this action.

57. That as a direct and proximate result of one or more of the foregoing unreasonably dangerous conditions of the Subject Heparin API, the Plaintiff, ARTEMUS BANKS, suffered serious physical, mental and emotional injuries, some or all of which are permanent in nature.

58. That as a result of the aforesaid injuries, Plaintiff, ARTEMUS BANKS, was caused to and will in the future experience great pain and suffering; has suffered and will in the future

suffer disability and disfigurement, has been caused to incur and will in the future incur expenses for necessary medical care, treatment and services, has suffered and will in the future suffer a loss of the value of his time, earnings, profits and salaries and has been and will be damaged in his earning capacity, and has otherwise been damaged in a personal and pecuniary nature.

WHEREFORE, Plaintiff, ARTEMUS BANKS, prays that judgment be entered in his favor and against the Defendant, SCIENTIFIC PROTEIN LABORATORIES, L.L.C., in a sum in excess of seventy-five thousand dollars ($75,000), exclusive of interest and costs of this action.

SIXTH CAUSE OF ACTION
Negligence – Scientific Protein Labs

59. Plaintiff repeats and incorporated by reference paragraphs 1 through 33 of this complaint as if fully set forth herein.

60. That it then and there became and was the duty of the Defendant, SCIENTIFIC PROTEIN LABORATORIES, L.L.C., to exercise ordinary care in its conduct so as not to cause injury to the person of the Plaintiff, ARTEMUS BANKS.

61. Notwithstanding, the Defendant, SCIENTIFIC PROTEIN LABORATORIES, L.L.C., breached its duty of care to the Plaintiff, ARTEMUS BANKS, through acts or omissions including but not limited to one or more of the following:

(a) negligently and carelessly procured bio-medical products from suppliers in China for use in pharmaceutical drugs in the United States, when the facilities and operations of those suppliers had never been properly or adequately inspected by or on behalf of Defendants, SCIENTIFIC PROTEIN LABORATORIES, L.L.C.;

(b) negligently and carelessly failed to properly and adequately inspect and test the Subject Heparin API for unsafe and dangerous impurities contained therein;

(c) negligently and carelessly failed to employ proper and adequate quality control procedures to ensure that its Subject Heparin API was safe and free from dangerous impurities;

(d) negligently and carelessly failed to properly supervise, monitor and/or oversee the acts and omissions of its global manufacturing operations and supply chain operations;

(e) negligently and carelessly failed to timely recall the Subject Heparin API or otherwise remedy the danger the product posed to consumers once the defendants, and each of them, became aware that a potential danger to consumers existed;

(f) negligently and carelessly manufactured, sold and distributed the Subject Heparin API containing animal cartilage and/or other impurities that were injurious to the human body;

(g) negligently and carelessly manufactured, sold and distributed the Subject Heparin API without proper and adequate warnings and/or instructions to assist consumers and health care providers in identifying adverse reactions arising from the condition of the product; and/or

(h) otherwise negligently and carelessly manufactured, sold and distributed the Subject Heparin API when it was in an unsafe and dangerous condition by way of its manufacture, distribution, sale, warnings and/or instructions in particulars to be determined through discovery in this action.

62. That as a direct and proximate result of one or more of the breach of duty by the Defendant, SCIENTIFIC PROTEIN LABORATORIES, L.L.C., the Plaintiff, ARTEMUS BANKS, suffered serious physical, mental and emotional injuries, some or all of which are permanent in nature.

63. That as a result of the aforesaid injuries, Plaintiff, ARTEMUS BANKS, was caused to and will in the future experience great pain and suffering, has suffered and will in the future suffer disability and disfigurement, has been caused to incur and will in the future incur expenses for necessary medical care, treatment and services, has suffered and will in the future suffer a

loss of the value of his time, earnings, profits and salaries and has been and will be damaged in his earning capacity, and has otherwise been damaged in a personal and pecuniary nature.

WHEREFORE, Plaintiff, ARTEMUS BANKS, prays that judgment be entered in his favor and against the Defendant, SCIENTIFIC PROTEIN LABORATORIES, L.L.C., in a sum in excess of seventy-five thousand dollars ($75,000), exclusive of interest and costs of this action.

SEVENTH CAUSE OF ACTION
Breach of Warranties – Scientific Protein Labs

64. Plaintiff repeats and incorporates by reference paragraphs 1 through 33 of this Complaint as fully set forth herein.

65. Defendant, SCIENTIFIC PROTEIN LABORATORIES, L.L.C., expressly and/or impliedly warranted and represented that the Subject Heparin API, including its instructions and warnings, conformed to manufacturing specifications, was proper and safe for the use for which it was manufactured and sold, and said defendant further warranted that the Subject Heparin API was free from defects.

66. Defendant, SCIENTIFIC PROTEIN LABORATORIES, L.L.C., breached said warranties in that the Subject Heparin API did not conform to manufacturing specifications, was not proper and safe for the use for which it was manufactured and sold, and further was not free from defects.

67. Plaintiff, ARTEMUS BANKS, by way of his purchase and/or receipt of the Subject Heparin Product containing the Subject Heparin API, was a beneficiary of the warranties extended by the Defendant, SCIENTIFIC PROTEIN LABORATORIES, L.L.C.

68. As a direct and proximate result of the foregoing breach of warranties, by the Defendant, SCIENTIFIC PROTEIN LABORATORIES, L.L.C., the Plaintiff, ARTEMUS BANKS, suffered serious physical, mental and emotional injuries, some or all of which are permanent in nature.

69. That as a result of the aforesaid injuries, Plaintiff, ARTEMUS BANKS, was caused to and will in the future experience great pain and suffering, has suffered and will in the future suffer disability and disfigurement, has been caused to incur and will in the future incur expenses for necessary medical care, treatment and services, has suffered and will in the future suffer a loss of the value of his time, earnings, profits and salaries and has been and will be damaged in his earning capacity, and has otherwise been damaged in a personal and pecuniary nature.

70. WHEREFORE, Plaintiff, ARTEMUS BANKS, prays that judgment be entered in his favor and against the Defendant, SCIENTIFIC PROTEIN LABORATORIES, L.L.C., in a sum in excess of seventy-five thousand dollars ($75,000), exclusive of interest and costs of this action.

EIGHTH CAUSE OF ACTION
Willful & Wanton Misconduct – Scientific Protein Laboratories

71. Plaintiff repeats and incorporates by reference paragraphs 1 through 33 and paragraphs 55 through 70 of this Complaint as fully set forth herein.

72. That the foregoing acts and omissions committed by the Defendant, SCIENTIFIC PROTEIN LABORATORIESS, L.L.C., were committed willfully and wantonly, were grossly negligent, and/or exhibited a conscious disregard for the safety and health of the general public, including the plaintiff.

73. That as a result of the willful, wanton, and grossly negligent misconduct of the Defendant, SCIENTIFIC PROTEIN LABORATORIESS, L.L.C., Plaintiff, ARTEMUS BANKS, suffered serious physical, mental and emotional injuries, some or all of which are permanent in nature.

74. That as a result of the aforesaid injuries, Plaintiff, ARTEMUS BANKS, was caused to and will in the future experience great pain and suffering, has suffered and will in the future suffer disability and disfigurement, has been caused to incur and will in the future incur expenses for necessary medical care, treatment and services, has suffered and will in the future suffer a loss of the value of his time, earnings, profits and salaries and has been and will be damaged in his earning capacity, and has otherwise been damaged in a personal and pecuniary nature.

WHEREFORE, Plaintiff, ARTEMUS BANKS, prays that judgment be entered in his favor and against the Defendant, SCIENTIFIC PROTEIN LABORATORIESS, L.L.C., for compensatory damages in a sum in excess of seventy-five thousand dollars ($75,000), exclusive of interest and costs of this action, and for punitive damages in the amount of one hundred million dollars ($100,000,000.00).

Respectfully Submitted,

Donald J. Nolan, Esq.
Paul R. Borth, Esq.
Jennifer L. Parker, Esq.
NOLAN LAW GROUP
20 North Clark Street, 30th Floor
Chicago, Illinois 60602-4109
Tel (312) 630-4000

Dated: April 23, 2008

EXHIBIT "B"

Baxter Healthcare Corporation 847.546.6311
Route 120 & Wilson Road
Round Lake, Illinois 60073-0490

Baxter

Urgent Product Recall

January 17, 2008

Re: Heparin Sodium Injection 1000 units/mL 10mL Vial
Lot #'s 107054 and 117085
Heparin Sodium Injection 1000 units/mL 30mL Vial
Lot #'s 047056, 097081, 107024, 107064, 107066, 107074, and 107111

Dear Customer/Wholesaler/Distributor:

Baxter Healthcare is performing a **voluntary recall** of the above lots of Heparin as a precaution due to an increase in reports of adverse patient reactions including abdominal pain, abdominal pain (upper), decreased blood pressure, burning sensation, chest pain, diarrhea, dizziness, drug ineffectiveness, dyspepsia, dyspnea, erythema, flushing, headache, hyperhidrosis, hypoesthesia, hypotension, lacrimation increased, loss of consciousness, malaise, nausea, pallor, palpitations, paresthesia, paresthesia (oral), pharyngeal edema, restlessness, vomiting/retching, stomach discomfort, tachycardia, thirst, trismus, and unresponsiveness to stimuli. We have received no reports involving fatality. Our records indicate that you have received the above affected Heparin Sodium 1000 unit/mL for injection manufactured by Baxter.

Baxter is in the process of an in-depth investigation to determine the root cause of the reported reactions.

NDC #	Lot #	Description	Expiration Date
0641244045	107054	Heparin 1000units/mL 10mL vial	10/2009
0641244045	117085	Heparin 1000units/mL 10mL vial	11/2009
0641245045	047056	Heparin 1000units/mL 30mL vial	10/2008
0641245045	097081	Heparin 1000units/mL 30mL vial	09/2009
0641245045	107024	Heparin 1000units/mL 30mL vial	10/2009
0641245045	107064	Heparin 1000units/mL 30mL vial	10/2009
0641245045	107066	Heparin 1000units/mL 30mL vial	10/2009
0641245045	107074	Heparin 1000units/mL 30mL vial	10/2009
0641245045	107111	Heparin 1000units/mL 30mL vial	10/2009

Please immediately discontinue use and segregate the above affected lot numbers.

Baxter

1. Examine your inventory to determine if you have any affected product. If so, remove the affected product from your inventory and contact Baxter Healthcare Center for Service at 1-888-229-0001 to arrange for return and credit.

2. If you have distributed the affected lot numbers of Heparin to other services or facilities, or if you are a dealer, wholesaler or distributor/reseller of any of the affected products, please forward this communication as appropriate. Any distributed product is to be returned according to this notification.

Please complete the attached reply form confirming your receipt of this letter and fax it to Baxter at the number provided on the form. Baxter is required by the FDA to obtain responses from our customers on notifications of this nature. Returning the form promptly will prevent you from receiving a repeat notice.

We appreciate your immediate attention and apologize for any inconvenience this may cause you or your staff. If you have any technical or clinical questions, please contact Baxter Healthcare Corporation Product Information Center at 1-800-933-0303.

The FDA has been notified of this communication.

Sincerely,

David Rohrbach
Vice President, Quality
Baxter Pharmaceuticals and Technologies
Baxter Healthcare Corporation

Baxter

Heparin Sodium Injection 1000 units/mL 10mL Vial
Heparin Sodium Injection 1000 units/mL 30mL Vial

CUSTOMER REPLY FORM
URGENT PRODUCT RECALL
January 17, 2008

NDC #	Lot #	Description
0641244045	107054, 117085	Heparin 1000units/mL 10mL vial
0641245045	047056, 097081, 107024, 107064, 107066, 107074, 107111	Heparin 1000units/mL 30mL vial

Please complete and return this form to the FAX number listed below as confirmation that you have received this notification. A fax cover sheet is not required.

1 (847) 270 5457

Facility Name and Address:	

☐ We have inventory of the affected lot numbers and have contacted Baxter to return affected product.

☐ We have no remaining inventory of the affected units.

We understand the contents of the letter, performed the actions as outlined in the letter as needed, and have disseminated this information to our staff and to other services or facilities, as applicable.

Signature/Date:
REQUIRED FIELD _____

Reply Confirmation Completed By: *(Please Print Name)*	
Title: *(Please Print)*	
Telephone Number (Including Area Code):	

2008-001-MD

EXHIBIT "C"

Baxter Healthcare Corporation 847.546.6311
Route 120 & Wilson Road
Round Lake, Illinois 60073-0490

Baxter

Urgent Product Recall

Additional Information

January 24, 2008

Re: Additional information concerning Heparin Sodium Injection 1000 units/mL 10mL Vial
Lot #'s 107054 and 117085
Heparin Sodium Injection 1000 units/mL 30mL Vial
Lot #'s 047056, 097081, 107024, 107064, 107066, 107074, and 107111

Dear Customer/Wholesaler/Distributor:

On January 17, 2008 Baxter Healthcare sent you an Urgent Product Recall letter (see attached) regarding a voluntary recall for the above lots of Heparin as a precaution due to an increase in reports of adverse patient reactions. We are now providing additional information to assist you in returning these lots.

1. The NDC numbers listed in the January 17, 2008 letters were for the 25 vial shelf packs. The individual vials within those shelf packs do not display the shelf pack NDC number. **Listed below are the NDC numbers referenced on the individual vials contained within those shelf packs.** Please note that the list of lot numbers has remained unchanged.

Heparin Sodium Injection 1000 units/mL 10 mL vial			
NDC# (on pack)	**NDC # (on vial)**	**Lot #**	**Expiration Date**
0641-2440-45	0641-2440-41	107054	10/2009
0641-2440-45	0641-2440-41	117085	11/2009

Heparin Sodium Injection 1000 units/mL 30 mL vial			
NDC# (on pack)	**NDC # (on vial)**	**Lot #**	**Expiration Date**
0641-2450-45	0641-2450-41	047056	10/2008
0641-2450-45	0641-2450-41	097081	09/2009
0641-2450-45	0641-2450-41	107024	10/2009
0641-2450-45	0641-2450-41	107064	10/2009
0641-2450-45	0641-2450-41	107066	10/2009
0641-2450-45	0641-2450-41	107074	10/2009
0641-2450-45	0641-2450-41	107111	10/2009

Baxter

Please immediately recheck your inventory of individual vials, discontinue the use of and segregate the affected lot numbers.

2. If you have any affected product, immediately remove it from your inventory.

   A. If you are a customer who purchased the affected lot numbers directly from Baxter, please contact the Baxter Pharmaceuticals and Technologies Customer Service at **1-800-667-0959,** to arrange for return and credit.

   B. If you are a customer who purchased the affected lot numbers through a distributor or wholesaler, you must go through the distributor or wholesaler to arrange for return and credit.

   C. If you have distributed the affected lot numbers of Heparin to other services or facilities, or if you are a dealer, wholesaler or distributor/reseller of any of the affected lot numbers, please forward this communication as appropriate. Any distributed product is to be returned according to this notification.

3. Please complete the attached reply form confirming your receipt of this letter and fax it to Baxter at the number provided on the form. Baxter is required by the FDA to obtain responses from all of our customers on notifications of this nature. Returning the form promptly will prevent you from receiving a repeat notice.

We appreciate your immediate attention and apologize for any inconvenience this may cause you or your staff.

The FDA has been notified of this communication.

Sincerely,

David Rohrbach

David Rohrbach
Vice President, Quality
Baxter Pharmaceuticals and Technologies
Baxter Healthcare Corporation

Enclosure: Heparin Sodium Injection Urgent Product Recall Letter – January 17, 2008

Baxter

HEPARIN SODIUM INJECTION 1000 UNITS/mL
CUSTOMER REPLY FORM - URGENT PRODUCT RECALL (Additional Information)
Letter Dated January 24, 2008

Heparin Sodium Injection 1000 units/mL 10 mL vial			
NDC# (on pack)	**NDC # (on vial)**	**Lot #**	**Expiration Date**
0641-2440-45	0641-2440-41	107054	10/2009
0641-2440-45	0641-2440-41	117085	11/2009

Heparin Sodium Injection 1000 units/mL 30 mL vial			
NDC# (on pack)	**NDC # (on vial)**	**Lot #**	**Expiration Date**
0641-2450-45	0641-2450-41	047056	10/2008
0641-2450-45	0641-2450-41	097081	09/2009
0641-2450-45	0641-2450-41	107024	10/2009
0641-2450-45	0641-2450-41	107064	10/2009
0641-2450-45	0641-2450-41	107066	10/2009
0641-2450-45	0641-2450-41	107074	10/2009
0641-2450-45	0641-2450-41	107111	10/2009

Please complete and return this form. FAX it to **1 (847) 270-5457** as confirmation that you have received this notification. A fax cover sheet is not required.

Facility Name and Address:	

☐ We have inventory of the affected lot numbers and have contacted Baxter or our supplier/distributor to return affected product.

☐ We have no remaining inventory of the affected lot numbers.

We understand the contents of the letter, performed the actions as outlined in the letter as needed, and have disseminated this information to our staff and to other services or facilities, as applicable.

Reply Confirmation Completed By: *(Please Print Name)*	
Title: *(Please Print)*	
Telephone Number (Including Area Code):	

Signature/Date:
(REQUIRED FIELD)

EXHIBIT "D"

Baxter Healthcare Corporation 847.546.6311
Route 120 & Wilson Road
Round Lake, Illinois 60073-0490

Baxter

Urgent Product Recall

February 29, 2008

Re: All Baxter Heparin Products of the following sizes
Heparin Sodium Injection 1000 units/mL - 1 mL, 10 mL and 30 mL Vials
Heparin Sodium Injection 5000 units/mL - 1 mL and 10 mL Vials
Heparin Sodium Injection 10,000 units/mL - 1 mL and 4 mL in 5 mL Vials

Dear Renal Home Patient:

As a precaution, Baxter Healthcare ("Baxter") is expanding its **voluntary recall of Heparin Sodium Injection to include all lots of single and multi-dose vial products,** due to an increase in reports of adverse patient reactions including stomach discomfort, belly pain, upset stomach, nausea, vomiting/dry heaves, diarrhea, **decreased or low blood pressure,** chest pain, fast heart rate, dizziness, fainting, unresponsiveness, shortness of breath, feeling your heart beat strong or fast, drug ineffectiveness, burning sensation, redness of the skin, paleness of the skin, abnormal sensation of the skin, flushing, increased sweating, decreased skin sensitivity, headache, feeling unwell, restlessness, watery eyes, abnormal sensation of the mouth or lips, throat swelling, thirst, and difficulty opening the mouth.

Our records indicate that you may have received the Heparin Sodium Injection (1000 units/mL, 5000 units/mL, or 10,000 units/mL) product manufactured by Baxter that is affected by this recall.

Please check your supplies immediately to determine if you have any of the above Baxter Heparin products.

Please note, if you have received a recent shipment of Heparin from Baxter, it may be APP/Abraxis Heparin. **The APP/Abraxis Heparin is acceptable for continued use and is not being recalled; only the Baxter Heparin identified above is being recalled.** APP/Abraxis is an alternate supplier of Heparin with whom Baxter has partnered to provide our home patients replacement product.

If you have any Baxter Heparin product, **discontinue use of the product,** segregate that product and contact Baxter Dialysis Patient Services at **1-800-284-4060** to arrange for the return.

Baxter

Baxter intends to send every patient a replacement order of his or her existing Heparin prescription within the next 14 calendar days. The replacement order will not be Baxter Heparin; it will be APP/Abraxis Heparin. We are working as quickly as possible to send these replacement products to each patient. However, if you have a concern regarding continuing your therapy until you receive the replacement product, please contact your dialysis center for further instruction.

Please complete the attached reply form confirming your receipt of this letter and return it to Baxter using the enclosed addressed and postage-paid envelope. Baxter is required by the FDA to obtain responses from our customers on notifications of this nature. Returning the form promptly will prevent you from receiving an additional notice.

We appreciate your immediate attention and apologize for any inconvenience this may cause you.

The FDA has been notified of this communication.

Sincerely,

Raymond Godlewski Sr. R.Ph.
Vice President, Quality
Baxter Pharmaceuticals and Technologies
Baxter Healthcare Corporation

Baxter

HOME PATIENT REPLY FORM
URGENT PRODUCT RECALL
February 29, 2008

Urgent Product Recall Applies to All Products Listed Below:

Heparin Sodium Injection 1000 units/mL - 1 mL, 10 mL and 30 mL Vials
Heparin Sodium Injection 5000 units/mL - 1 mL and 10 mL Vials
Heparin Sodium Injection 10,000 units/mL - 1 mL and 4 mL in 5 mL Vials

Please complete and return this record to us either using the self-addressed stamped envelope attached or by FAX to 1-847-270-5457.

Patient Name and Address: *(Please Print)*	
Reply Confirmation Completed By: *(Please Print Name)*	
Telephone Number: *(Including Area Code)*	

☐ I have the product affected by this recall in my possession and have contacted Baxter to arrange its return.

☐ I have no product affected by this recall in my possession.

Signature/Date:
REQUIRED FIELD _____

Baxter Healthcare Corporation 847.546.6311
Route 120 & Wilson Road
Round Lake Illinois 60073-0490

Baxter

Urgent Product Recall

February 29, 2008

Re: All Lots Within Expiry for the Following Products:
Heparin Sodium Injection 1000 units/mL - 1 mL, 10mL and 30 mL Vials
Heparin Sodium Injection 5000 units/mL - 1 mL and 10 mL Vials
Heparin Sodium Injection 10,000 units/mL - 1 mL and 4 mL in 5 mL Vials

Dear Customer/Wholesaler/Distributor/Dialysis Center:

As a precaution, Baxter Healthcare ("Baxter") is expanding its **voluntary recall of Heparin Sodium Injection to include all lots of single and multi-dose vial products**, due to an increase in reports of adverse patient reactions including abdominal pain, burning sensation, chest pain, diarrhea, dizziness, drug ineffectiveness, dyspepsia, dyspnea, erythema, flushing, headache, hyperhidrosis, hypoesthesia, hypotension, **including profound and refractory hypotension,** increased lacrimation, loss of consciousness, malaise, nausea, pallor, palpitations, paresthesia, paresthesia (oral), pharyngeal edema, restlessness, vomiting/retching, stomach discomfort, tachycardia, thirst, trismus, and unresponsiveness to stimuli. **The reports of profound and refractory hypotension usually occur within the first few minutes of bolus administration.**

Baxter has been in communication with the FDA to assure availability of single and multi-dose vial products prior to initiating this recall action. FDA has confirmed that alternate suppliers of Heparin vial products are now able to supply the market while Baxter is in the process of performing an in-depth investigation to determine the root cause of the reported reactions.

Please immediately discontinue use and segregate the product listed below:

Heparin Sodium Injection 1000 units/mL - 1 mL vial		Heparin Sodium Injection 1000 units/mL - 10 mL vial		Heparin Sodium Injection 1000 units/mL - 30 mL vial	
NDC# (on pack)	NDC# (on vial)	NDC# (on pack)	NDC# (on vial)	NDC# (on pack)	NDC# (on vial)
0641-0391-25	0641-0391-21	0641-2440-45	0641-2440-41	0641-2450-45	0641-2450-41
0641-0391-02	0641-0391-64				

Heparin Sodium Injection 5000 units/mL - 1 mL vial		Heparin Sodium Injection 5000 units/mL - 10 mL vial	
NDC# (on pack)	NDC # (on vial)	NDC# (on pack)	NDC # (on vial)
0641-0400-25	0641-0400-21	0641-2460-45	0641-2460-41
0641-0400-02	0641-0400-64		

Heparin Sodium Injection 10,000 units/mL - 1 mL vial		Heparin Sodium Injection 10,000 units/mL - 4 mL in 5 mL vial	
NDC# (on pack)	NDC # (on vial)	NDC # (on vial)	NDC# (on vial)
0641-0410-25	0641-0410-21	0641-2470-45	0641-2470-41
0641-0410-02	0641-0410-64		

Baxter

Dialysis Center Customers Only:

Baxter will send a notification to home patients who have potentially received the affected Heparin product from Baxter (See attached notification to Home Patient). We are working with these patients to retrieve the affected product and provide replacement Heparin from an alternate supplier (APP/Abraxis) as quickly as possible. If your patients are using Heparin from Baxter, they will be receiving the attached patient letter informing them of the recall for the above specified products.

Wholesalers and Distributors:

1. If you are a customer who purchased the affected Heparin product directly from Baxter, please contact Baxter Pharmaceuticals and Technologies Customer Service at 1-800-667-0959, to arrange for return and credit. In order to expedite this process, please have your Lot# and Product Quantity Information available.

2. If you are a customer who purchased the affected Heparin product through a distributor or wholesaler, you must go through the distributor or wholesaler to arrange for return and credit.

3. If you have distributed the affected Heparin product to other services or facilities, or if you are a dealer, wholesaler or distributor/reseller (including the repackaging and redistribution) of any of the affected products, please forward this communication as appropriate. Any distributed product is to be returned according to this notification.

Baxter is required by the FDA to obtain responses from all of our customers on notifications of this nature.

Please complete the attached reply form confirming your receipt of this letter and fax it to Baxter at the number provided on the form. Returning the form promptly will prevent you from receiving a repeat notice. If you are affected by the previous Heparin recall (initiated in January 2008), please immediately discontinue use, segregate the affected product and return as directed above.

We appreciate your immediate attention and apologize for the inconvenience this may cause you or your staff.

The FDA has been notified of this communication.

Sincerely,

Raymond Godlewski Sr. R.Ph.
Vice President, Quality
Baxter Pharmaceuticals and Technologies
Baxter Healthcare Corporation

Baxter

CUSTOMER REPLY FORM - URGENT PRODUCT RECALL
February 29, 2008

Urgent Product Recall Applies to All Products Listed Below:

Heparin Sodium Injection 1000 units/mL - 1 mL vial		Heparin Sodium Injection 1000 units/mL - 10 mL vial		Heparin Sodium Injection 1000 units/mL - 30 mL vial	
NDC# (on pack)	NDC# (on vial)	NDC# (on pack)	NDC# (on vial)	NDC# (on pack)	NDC# (on vial)
0641-0391-25	0641-0391-21	0641-2440-45	0641-2440-41	0641-2450-45	0641-2450-41
0641-0391-02	0641-0391-64				

Heparin Sodium Injection 5000 units/mL - 1 mL vial		Heparin Sodium Injection 5000 units/mL - 10 mL vial	
NDC# (on pack)	NDC # (on vial)	NDC# (on pack)	NDC # (on vial)
0641-0400-25	0641-0400-21	0641-2460-45	0641-2460-41
0641-0400-02	0641-0400-64		

Heparin Sodium Injection 10,000 units/mL - 1 mL vial		Heparin Sodium Injection 10,000 units/mL - 4 mL in 5 mL vial	
NDC# (on pack)	NDC # (on vial)	NDC # (on vial)	NDC# (on vial)
0641-0410-25	0641-0410-21	0641-2470-45	0641-2470-41
0641-0410-02	0641-0410-64		

Please complete and return this form to the FAX number listed below as confirmation that you have received this notification. A fax cover sheet is not required.

1 (847) 270-5457

Facility Name and Address:	

☐ We have the affected product in our inventory and have contacted Baxter to arrange for its return.

☐ We have no remaining inventory of the affected product.

We understand the contents of the letter, performed the actions as outlined in the letter as needed, and have disseminated this information to our staff and to other services or facilities, as applicable.

Signature/Date:
REQUIRED FIELD

Reply Confirmation Completed By: *(Please Print Name)*	
Title: *(Please Print)*	
Telephone Number: (Including Area Code)	

Baxter Healthcare Corporation 847.546.6311
Route 120 & Wilson Road
Round Lake, Illinois 60073-0490

Baxter

Urgent Product Recall

February 29, 2008

RE: HEP-LOCK (Heparin Lock Flush Solution, USP) and
HEP-LOCK U/P (Preservative-Free Heparin Lock Flush Solution, USP)

All Lots of the Following Products:

NDC# on 25 pack	NDC# on Vial	Description
0641-0387-25	0641-0387-21	Hep-Lock 100 u/mL - 2 mL Vial
0641-0389-25	0641-0389-21	Hep-Lock 100 u/mL - 1 mL Vial
0641-0392-25	0641-0392-21	Hep-Lock 10 u/mL - 1 mL Vial
0641-0393-25	0641-0393-21	Hep-Lock 10 u/mL - 2 mL Vial
0641-2436-45	0641-2436-41	Hep-Lock 100 u/mL - 10 mL Vial
0641-2438-45	0641-2438-41	Hep-Lock 10 u/mL - 10 mL Vial
0641-2442-45	0641-2442-41	Hep-Lock 10 u/mL - 30 mL Vial
0641-2443-45	0641-2443-41	Hep-Lock 100 u/mL - 30 mL Vial
0641-0272-25	0641-0272-21	Hep-Lock U/P 10 u/mL - 1 mL Vial
0641-0273-25	0641-0273-21	Hep-Lock U/P 100 u/mL - 1 mL Vial

Dear Customer/Wholesaler/Distributor/Dialysis Center:

As a precaution, Baxter Healthcare ("Baxter") is expanding its **voluntary recall of Baxter Heparin products to include all lots of HEP-LOCK (Heparin Lock Flush Solution, USP) and HEP-LOCK U/P (Preservative-Free Heparin Lock Flush Solution, USP) products.** These products utilize the same active pharmaceutical ingredient (API) source as the recalled Baxter Heparin Sodium for Injection single and multi-dose vial products.

Reports of adverse events have been associated with the multi-dose products, and Baxter is taking the precautionary step of recalling all remaining heparin flush products that are currently on the market. While the API has not been implicated as the cause of these increased adverse events, Baxter is recalling all products utilizing this API source.

Baxter has been in communication with the FDA to assure availability of Hep-Lock products prior to initiating this recall action. FDA has confirmed that alternate suppliers of Hep-Lock products are able to supply the healthcare needs while Baxter is in the process of performing an in-depth investigation to determine the root cause of the reported reactions.

Please immediately discontinue use and segregate the products listed above.

Baxter

Customer/Wholesaler/Distributor/Dialysis Center:

1. If you are a customer who purchased the affected Hep-Lock product directly from Baxter, please contact Baxter Pharmaceuticals and Technologies Customer Service Monday through Friday, 7 A.M. to 6 P.M. Central Standard Time at 1-800-667-0959, to arrange for return and credit. In order to expedite this process, please have your Lot# and Product Quantity information available.

2. If you are a customer who purchased the affected Hep-Lock product through a distributor or wholesaler, you must go through the distributor or wholesaler to arrange for return and credit.

3. If you have distributed the affected Hep-Lock product to other services or facilities, or if you are a dealer, wholesaler or distributor/reseller (including the repackaging and redistribution) of any of the affected products, please forward this communication as appropriate. Any distributed product is to be returned according to this notification.

Please complete the attached reply form confirming your receipt of this letter and fax it to Baxter at the number provided on the form. Returning the form promptly will prevent you from receiving a repeat notice.

We appreciate your immediate attention and apologize for the inconvenience this may cause you or your staff.

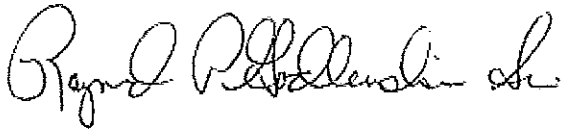
Baxter is required by the FDA to obtain responses from all of our customers on notifications of this nature.

The FDA has been notified of this communication.

Any adverse reactions experienced with the use of this product, and/or quality problems should also be reported to the FDA's MedWatch Program on the MedWatch website at www.fda.gov/medwatch by telephone at 1-800-FDA-1088, by Fax at 1-800-FDA-0178, or by mail at:

MedWatch
HF-2, FDA
5600 Fishers Lane
Rockville, MD 20852-9787

Sincerely,



Raymond P. Godlewski Sr. R.Ph.
Vice President, Quality
Baxter Pharmaceuticals and Technologies
Baxter Healthcare Corporation

Baxter

CUSTOMER REPLY FORM - URGENT PRODUCT RECALL
February 29, 2008

Urgent Product Recall Applies to All Products Listed Below:

NDC# on 25 pack	NDC# on Vial	Description
0641-0387-25	0641-0387-21	Hep-Lock 100 u/mL - 2 mL Vial
0641-0389-25	0641-0389-21	Hep-Lock 100 u/mL - 1 mL Vial
0641-0392-25	0641-0392-21	Hep-Lock 10 u/mL - 1 mL Vial
0641-0393-25	0641-0393-21	Hep-Lock 10 u/mL - 2 mL Vial
0641-2436-45	0641-2436-41	Hep-Lock 100 u/mL - 10 mL Vial
0641-2438-45	0641-2438-41	Hep-Lock 10 u/mL - 10 mL Vial
0641-2442-45	0641-2442-41	Hep-Lock 10 u/mL - 30 mL Vial
0641-2443-45	0641-2443-41	Hep-Lock 100 u/mL - 30 mL Vial
0641-0272-25	0641-0272-21	Hep-Lock U/P 10 u/mL - 1 mL Vial
0641-0273-25	0641-0273-21	Hep-Lock U/P 100 u/mL - 1 mL Vial

Please complete and return this form to the FAX number listed below as confirmation that you have received this notification. A fax cover sheet is not required.

1 (847) 270-5457

Facility Name and Address:	

☐ We have the affected product in our inventory and have contacted Baxter to arrange for its return.

The number of vials/units being returned are (Lot number(s) and quantity):_____

☐ We have no remaining inventory of the affected product.

We understand the contents of the letter, performed the actions as outlined in the letter as needed, and have disseminated this information to our staff and to other services or facilities, as applicable.

I have knowledge of the HEP-LOCK products at our facility:
Signature/Date:_____

REQUIRED FIELD

Reply Confirmation Completed By: *(Please Print Name)*	
Title: *(Please Print)*	
Telephone Number (Including Area Code):	

EXHIBIT "E"

Fresenius Medical Care

*** URGENT Baxter Heparin Recall ***

To: FMCNA Baxter Heparin Customers/Patients **Date:** March 12, 2008

Re: **Baxter Heparin Sodium Injection Recall**

All Baxter Heparin Products of the following sizes:
Heparin Sodium Injection 1,000 units/mL – 1 mL, 10 mL and 30 mL vials
Heparin Sodium Injection 5,000 units/mL – 1 mL and 10 mL vials
Heparin Sodium Injection 10,000 units/mL – 1 mL and 4 mL in 5 mL vials

This notification is to inform you of a very important product recall. **Baxter is voluntarily recalling all lots of single and multi-dose vial Heparin Sodium Injection products** due to reports of adverse patient reactions.

Our records indicate that you may have received the Heparin Sodium Injection (1,000 units/mL and 5,000 units/mL) product manufactured by Baxter that is affected by this recall.

Please check your supplies immediately. If you have any Baxter heparin product, discontinue its use immediately and segregate the product. Contact Fresenius Medical Care Customer Service at 1-800-323-5188 for instructions on how to return the recalled product.

Please note that any Heparin Sodium Injection product made by APP Pharmaceuticals, labeled APP Pharmaceuticals or Abraxis is acceptable for use and is not affected by this recall.

Baxter Healthcare is performing a voluntary recall of all Heparin lots as a precaution due to an increase in reports of adverse patient reactions including stomach discomfort, belly pain, upset stomach, nausea, vomiting/dry heaves, diarrhea, decreased or low blood pressure, chest pain, fast heart rate, dizziness, fainting, unresponsiveness, shortness of breath, feeling your heart beat strong or fast, drug ineffectiveness, burning sensation, redness of skin, paleness of the skin, abnormal sensation of the skin, flushing, increased sweating, decreased skin sensitivity, headache, feeling unwell, restlessness, watery eyes, abnormal sensation of the mouth or lips, throat swelling, thirst and difficulty opening mouth.

Continued on Back

Fresenius Medical Care

For any additional information about this recall you should go to Baxter Healthcare's website, www.baxter.com, or contact Baxter Dialysis Patient Services at 1-800-284-4060.

We appreciate your immediate attention to this matter and apologize for any inconvenience.

If you have any additional questions, please contact me at 781-699-4475

Sincerely,

Janet C. Kay, RAC
Manager Regulatory Affairs

EXHIBIT "F"

NOLAN LAW GROUP

20 NORTH CLARK 30TH FLOOR CHICAGO, ILLINOIS 60602 • P 312.630.4000 • F 312.630.4011 • TF 888.630.9340

3074 MADISON ROAD CINCINNATI, OHIO 45209 • P 513.533.2026 • F 513.721.2301

WWW.NOLAN-LAW.COM • CONTACT@NOLAN-LAW.COM

May 8, 2008

Via Facsimile 312-861-2200 *& U.S. Mail*

Ms. Leslie M. Smith, P.C.
Kirkland & Ellis, LLP
200 East Randolph Drive
Chicago, Illinois 60601-6636

Re: ***Artemus Banks v. Baxter Intl., Inc., et al.*** **08-cv-03524**

Dear Ms. Smith:

I write to memorialize our telephone conversations from May 7, 2008 regarding plaintiff's proposed stipulation protecting and preserving all returned Heparin subject to the recalls including the Heparin from Lot Number 027020 and bearing the corresponding NDC 0641-2450-41.

You stated that your client has already taken steps to preserve the Heparin subject to the consumer recalls. Further, you elaborated that any Heparin returned by a consumer or health care provider is being retained by Baxter. You further stated that samples are being preserved and set aside before the product is subjected to testing.

You also indicated that an inventory of the Heparin in the possession of the FDA may also be available to plaintiff. We request documentation respecting the transfer of all Heparin to the FDA.

While you stated that Baxter would generally be agreeable to entering into a stipulated order protecting and preserving the abovementioned Heparin, you also stated that Baxter prefers not to file a stipulation with the Court before the JPMDL rules.

It is plaintiff's position, however, that the Heparin subject to the recall could potentially be subject to testing, the nature of which may affect the integrity of the product or result in the complete destruction of the product tested. It is also known to plaintiff that the Heparin retained or otherwise possessed by Baxter carries expiration dates that may impact the validity of future testing.

Given the foregoing, and the immediacy of these issues, plaintiff requests that Baxter stipulate to an order protecting and preserving the recalled Heparin, particularly from Lot Number 027020 and bearing the corresponding NDC 0641-2450-41.

In addition, we are requesting that Baxter provide plaintiff with the testing protocols in place and in use by Baxter for the testing and analysis of Heparin products for OSCS.

At your earliest convenience, please contact our office to discuss this matter further so that an accord may be reached without intervention from the Court.

Very truly yours,

NOLAN LAW GROUP

Mollie E. O'Brien

********** -COMM. JOURNAL- ********** DATE MAY-08-2008 ***** TIME 09:45 *********

MODE = MEMORY TRANSMISSION START=MAY-08 09:43 END=MAY-08 09:45

FILE NO.=064

STN NO.	COMM.	ABBR NO.	STATION NAME/TEL NO.	PAGES	DURATION
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-NOLAN LAW GROUP -

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WWW.NOLAN-LAW.COM • CONTACT@NOLAN-LAW.COM

F A C S I M I L E

Date: May 8, 2008

Pages to follow: Two (2)

To: Ms. Leslie M. Smith, P.C. (312) 861.2200
Kirkland & Ellis, LLP

Re: *Artemus Banks v. Baxter Intl., Inc., et al*; 08-cv-03524

From: Mollie E. O'Brien/Tom Ellis

COMMENTS:

IF ANY PROBLEMS RESULT WITH THIS TRANSMISSION, PLEASE CONTACT THE PERSON LISTED ABOVE

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

ARTEMUS BANKS, Plaintiff, v. BAXTER INTERNATIONAL, INC., a corporation; BAXTER HEALTHCARE CORPORATION, a corporation, and SCIENTIFIC PROTEIN LABORATORIES, LLC, a limited liability company, ROBERT L. PARKINSON, JR., JAMES M. GATLING, and DAVID ROHRBACH, Defendants.	)	Case No. 08-cv-02324 Hon. Judge Robert W.Gettleman Magistrate Judge Mason

PROPOSED ORDER

On May 14, 2008 at _____Plaintiff's Motion for Order to Preserve Evidence came before this Court for hearing. This Court having reviewed and considered the moving papers and opposition thereto and argument on the matter, **IT IS HEREBY ORDERED:**

Plaintiff's Motion for Order to Preserve Evidence is granted and defendants shall preserve and protect all Heparin products returned to them or otherwise in their possession including that from Lot Number 027020 and those bearing NDC 0641-2450-41 until further order of Court.

IT IS SO ORDERED:

_____
United States District Judge

Date: _____